UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,695	04/12/2001	Michael F. Weiser	B0410/7277	7619

22832 7590 09/23/2002

KIRKPATRICK & LOCKHART LLP
75 STATE STREET
BOSTON, MA 02109-1808

EXAMINER
HAMILTON, LALITA M

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 09/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,695	WEISER ET AL.	
	Examiner	Art Unit	
	Lalita M Hamilton	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-49 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Drawings

The drawings are objected to for the following reasons:

In the specification-

Reference numeral 6 is designated as being both "myocardium" and "tissue".

Reference numeral 18 is designated as being both "proximal coil" and "distal coil".

Reference numeral 40 is designated as being "implant", "tapered coil", and "device".

Reference numeral 120 is designated as being both "broad coil" and "individual turns".

Reference numerals 52, 82, 148, and 149 are not in the specification.

In the drawings-

Reference numeral 28 and the "neck" in claims 31-33 are not shown in the drawings.

Specification

The disclosure is objected to because of the following informalities: The continuation data is not present in the first paragraph. Appropriate correction is required.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

There is no support in the specification as to what constitutes a "clinically effective penetration depth" in claim 38.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-41 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for not specifying structural limitations. "Configured to resist migration in the tissue" is vague and indefinite.

In claim 2, it is unclear how the "proximal end has a larger profile than the proximal end" and "proximal end" lacks antecedent basis.

In claim 9, it is unclear what constitutes "adequate longitudinal flexibility".

In claim 11, it is unclear how the surgical adhesive is "associated with the device".

In claim 20, term "individual coils" lacks antecedent basis.

In claim 21, the term "coil" lacks antecedent basis.

In claim 22, the term "coils" lacks antecedent basis.

In claims 26-29, the terms "broad loop" and "broad loop coil" lack antecedent basis.

In claim 30, the term "broadly wound core" lacks antecedent basis.

In claims 31-33, the "neck portion" is not shown in the drawings.

In claim 38, it is unclear what constitutes a "clinically effective penetration depth".

In claims 38, the term "implant delivery device" lacks antecedent basis.

In claim 42, there is no method step claimed.

In claim 49, it is unclear what constitutes "sufficient longitudinal flexibility".

The remaining rejected claims are rejected to because of their dependency upon the above rejected claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim (6,007,544). *Note: The date used for this reference is the filing date of June 14, 1996.*

Kim discloses an implant device that is configured to resist migration in the tissue (fig.38B) comprising a flexible body (col.24, lines 52-53) having proximal and distal portions each defining a profile, the proximal end larger than the distal end, a flexible body defining an hollow interior with at least one opening between the interior and exterior (col.20, lines 60-67 and col.28, lines 1-2), a tail at the proximal portion (fig.38B: 402) configured to remain at the tissue surface when the device is implanted (col.24, lines 1-18) and configured to be implanted into the tissue when the body of the device is implanted, a helical spring for the flexible body, configured to resist migration by exhibiting adequate longitudinal flexibility to substantially absorb migratory forces, a surgical adhesive associated with the device (col.33, lines 60-67), a helical spring of varying flexibility along its length (col.27, line 50 to col.28, line 17), the helical spring formed of a filament comprising a plurality of materials of varying moduli of elasticity (col.19, lines 45-48), flexibility created by varying the distance between the coils (fig.38B), a helical spring having constantly increasing diameter from the proximal portion to the distal portion wherein the coils of the distal portion define a constant diameter and the coils of the proximal portion define an increasing diameter in the proximal portion (fig.38B), helical spring having varying thickness along its length (col.21, lines 12-15), the flexible body comprising a helical spring and the tail comprises a broadly wound most proximal coil of the spring having a diameter that is greater than

the diameter of the coils of the body of the device (fig.38B), and the broadly wound coil being concentric with the body of the device (fig.38B).

Claims 38, 40, 42, 45, and 49 are rejected under 35 U.S.C. 102(a) as being anticipated by Hussein ('836). *Note: The date used for this reference is the filing date of March 4,1996.*

Hussein discloses an implant device and method of implanting comprising the steps of providing an implant device having a flexible body with the proximal and distal ends and an anchoring tail at the proximal tail (col.2, lines 30-31 and 47) and (fig.8a-l), providing a sharp tip delivery device configured to penetrate tissue and releasably retain the tissue implant device (43), associating the implant device with the implant delivery device, accessing the desired tissue implant site, withdrawing the implant delivery device from the implanted implant device, the implant and delivery device is rotated while penetrating forces are applied to screw the device into the tissue (col.4: 2), the tail of the implant device is submerged below the surface of the tissue after implantation (fig.8i), providing a tissue implant device that does not migrate from the tissue after implantation (col:2, lines 30-36 and col.3, lines 36-39), the device delivered surgically to the intended tissue location, providing a flexible spring body implant device having sufficient longitudinal flexibility to absorb migratory forces applied on the device by surrounding tissue after implantation, and inserting the flexible spring body into the tissue (col.2, line 47 and col.3, lines 35-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Whalen (4,130,904)

Kim discloses the invention substantially as claimed; however, Kim does not disclose a tail that includes a proximal end that is secured to the broadly wound coil, the proximal end joined to the broad loop by being wrapped about the loop, or the proximal end joined to the broad loop coil by welding or a malleable sleeve. Whalen teaches a flexible helical spring (col.1, lines 48-53) comprising a helically wound coil having a proximal end secured to the broadly wound coil (fig.2: 30 and 34), the proximal end joined to the broad loop coil by being wrapped around the loop (fig.2), and welding as a means of securing (col.2, lines 40-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a tail that includes a proximal end that is secured to the broadly wound coil and the proximal end joined to the broad loop by being wrapped about the loop in order to provide a means of maintaining the coils in a circular shape and the proximal end joined to the broad loop coil either by welding or a malleable sleeve as alternative means of securing.

Claims 30 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Wijay (5,824,059).

Kim discloses the invention substantially as claimed and further discloses that the device may be malleable into any shape or configuration (col.18, lines 14-16). However, Kim does not disclose a broadly wound core that is non-circular, the helical spring having a non-circular cross-sectional shape, the cross-sectional shape of the filament being rectangular, substantially perpendicular to the longitudinal axis of the device, or the cross section at an acute angle to the longitudinal axis of the device. Wijaya teaches teaches that it is well known in the art to use helical stents (col.1, lines 16-24) and further teaches a flexible stent comprising a rectangular cross-section (fig.1-2 and col.6, lines 10-20). It would have been obvious to one having ordinary skill in the art to incorporate a broadly wound core that is non-circular, the cross-sectional shape of the filament being rectangular, substantially perpendicular to the longitudinal axis of the device, and the cross section at an acute angle to the longitudinal axis of the device to provide an alternative means of preventing migration of the device.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim and Whalen as applied to claim 25 above, and further in view of Hussein (5,810,836).

Kim discloses and Whalen teaches the invention substantially as claimed; however, neither reference discloses nor teaches a neck portion comprising a straight line segment that lies in a plane substantially parallel to the longitudinal axis of the device. Hussein teaches a stent comprising a helical body having a neck portion having a straight-line segment (fig.5) and lying in a plane substantially parallel to the longitudinal axis of the device. It would have been obvious to one having ordinary skill

in the art at the time the invention was made to incorporate a neck portion comprising a straight line segment that lies in a plane substantially parallel to the longitudinal axis of the device to provide an alternative means of preventing migration of the device.

Claims 39, 41, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein.

Hussein discloses the invention substantially as claimed and an alternative embodiment where the implant remains exposed at the surface of the tissue after implantation (fig.1); however, Hussein does not disclose the device being delivered percutaneously or transthoracically or applying a penetrating force to the implant and implant delivery device combination such that the combination penetrates tissue to a clinically effective penetration depth to implant the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the method of delivering the device percutaneously and transthoracically in order to provide an alternative means of delivery and to apply a penetrating force to the implant and implant delivery device combination in order to ensure that the combination penetrates tissue to a clinically effective penetration depth to implant the device.

Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein in view of Murphy-Chutorian ('133).

Hussein discloses the invention substantially as claimed; however, Hussein does not disclose the method of applying surgical adhesive at the site of the implant after implantation. It is inherent that adhesive may be applied to the body prior to implantation. Murphy-Chutorian teaches a method of securing a stent to the tissue

using surgical adhesive (col.13, lines 45-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the method of applying surgical adhesive at the site of the implant prior to or after implantation in order to provide an alternative means of preventing migration of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2272.

LMH

JUSTINE R. YU
PRIMARY EXAMINER

September 18, 2002